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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/303,040 04/30/99 WINSLOW В 54957-B/JPW/ **EXAMINER** Г HM22/0620 PAMELA G. SALKELD, ESQ. PARK, H SCHERING-PLOUGH CORPORATION, PATENT DEPA ART UNIT PAPER NUMBER 2000 GALLOPING HILL ROAD, BUILDING K-6-1 MAILSTOP 1990 1648 KENILWORTH NJ 07033 DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No. 09/303.040

Applicant(s)

Examiner

Office Action Summary

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HANKYEL T. PARK, PH.D.

WINSLOW ET AL.

Art Unit 1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on Apr 3, 2001 2b) X This action is non-final. 2a) This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 37-74 is/are pending in the application. 4a) Of the above, claim(s) 61-68 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) X Claim(s) 37-60 and 69-74 is/are rejected. 7) Claim(s) is/are objected to. are subject to restriction and/or election requirement. 8) Claims **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are objected to by the Examiner. 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s).

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

20) Other:

19) Notice of Informal Patent Application (PTO-152)

Application/Control Number: 09/303,040 Page 2

Art Unit: 1648

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648.**

- 2. The request for filing continued prosecution application (CPA) on April 03, 2001 is acknowledged. At the time of filing of the CPA, the previous attorney requested the Office to "enter the unentered amendment previously filed on September 25, 2000." However, the Office never received such an amendment.
- 3. Claims 37-74 are pending. Applicants elect with traverse Group I. Applicants' argument regarding rejoining of Groups I and II and also rejoining of groups III and IV is persuasive; thus, rejoined claims 37-60 and 69-74 of Groups I and II will be examined. Claims 61-68 are withdrawn as nonelected claims.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 37-60 and 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of

Application/Control Number: 09/303,040 Page 3

Art Unit: 1648

"capable of being expressed", since the term "capable" is not a definitive term. It either expresses or doesn't.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 37-60 and 69-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for manipulation of the expression of feline CD86, feline CTLA-4 and their ligands feline CD80 and feline CD86 costimulatory molecules in order to regulate T-cell responses, through augmentation, suppression or redirection, to raise a desired immune response towards a particular feline pathogen or feline disease condition (page 2, lines 30-36), does not reasonably provide enablement for a recombinant virus comprising less than the all the components listed above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicants have not provided any data in regards to a recombinant virus comprising one foreign nucleic acid that would function as a vaccine as defined in the specification (page 2, line 36 to page 3, line 6). Lacking any convincing evidence to the contrary, Applicants have not enabled the invention.

1

Application/Control Number: 09/303,040

Art Unit: 1648

8. No claim is allowed.

9. Papers relating to this application may be submitted to Group 1600 by facsimile

transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number

for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive

transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform

with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner

should be directed to Hankyel T. Park, Ph.D., whose telephone number is (703) 305-7255. The

Examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 6:30 AM-

4:00 PM, (EST). The Examiner can also be reached on alternate Wednesdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's

Supervisor, James C. Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be

directed to the Group receptionist whose telephone number is (703) 308-0196.

Hankyel T. Park, Ph.D.

June 16, 2001

IANKYEL T. PARK, PH.D

Page 4

RIMARY EXAMINER